SUPREME COURT, No. 59

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Supreme Court of the United States

OCTOBER TERM, 1966

ABBOTT LABORATORIES, ET AL., *Petitioners*,

v.

JOHN W. GARDNER, Secretary of Health, Education, and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents*.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONERS

Of Counsel:

STANLEY L. TEMKO
HERBERT DYM
COVINGTON & BURLING
701 Union Trust Building
Washington 5, D. C.

HAYWARD H. COBURN
DRINKER BIDDLE & REATH
1100 Philadelphia National Bank Building
Broad and Chestnut Streets
Philadelphia 7, Pennsylvania
Attorney for Merck & Co., Inc.

LLOYD N. CUTLER
MARSHALL HORNBLOWER
WILMER, CUTLER & PICKERING
900 17th Street, N. W.
Washington 6, D. C.

C. JOSEPH STETLER
JOHN K. WORLEY
Pharmaceutical Manufacturers Association
1155 15th Street, N. W.
Washington 5, D. C.
Attorneys for Pharmaceutical Manufacturers Association

ALEXANDER L. NICHOLS
WILLIAM S. MEGONIGAL, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL
3000 DuPont Building
Wilmington 1, Delaware
Attorneys for Petitioners

GERHARD A. GESELL
701 Union Trust Building
Washington 5, D. C.,
Attorney for Petitioners

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Supreme Court of the United States

OCTOBER TERM, 1966

No. 39

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education, and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONERS

Respondents continue their attempt to deprive petitioners of a fundamental right recognized as long ago as *Philadelphia Co.* v. *Stimson,* 223 U. S. 605 (1912)—the right to challenge in the Federal courts the legality of official actions vitally affecting petitioners' businesses. Respondents urge that petitioners should be required to operate their businesses under a cloud, acting at their peril in violating the regulations involved in this case, and awaiting respondents' decision to enforce the regulations somewhere in some manner against somebody at some time. An entire industry, respondents suggest, cannot have its day in court to determine whether respondents' regulations are unlawful and then proceed under an established rule of law equally applicable to all its members.

This result is directly contrary to the purpose of Congress in enacting the Declaratory Judgment Act. (See Pet. Br. 15-16.) It cannot be supported in common sense, for it is neither practical nor equitable. The validity of the regulations may be reviewed in an action of this kind. Indeed, respondents themselves, when they back away from the pro-

cedural obstacles they have concocted, ask this Court to pass on the issue presented by the cross-motions for summary judgment because it

> "is purely legal and requires no weighing of testimony or other evidence; the district court reached and decided the question; . . . the question would be purely one of statutory construction and it concerns nearly all of the drug industry. . . ."

At this point they urge that "there is a public interest in enforcing the regulations if they be valid. . . ." (Res. Br. 55-56). Petitioners would add that there is also a public interest in preventing enforcement of the regulations if they are invalid, and that it is for these reasons among others that the District Court was correct in holding that the action presented a ripe, justiciable issue.

Petitioners will first reply to respondents' efforts to bar the courts to petitioners.[1] Thereafter, so that petitioners' position on the merits will be before the Court should it determine to decide the merits rather than to remand the case to the Court of Appeals, petitioners will deal with respondents' contention that the regulations are not invalid.

I. THE REGULATIONS ARE REVIEWABLE IN THIS ACTION

Petitioners' main brief (pp. 23-40) pointed out the errors committed by the Court of Appeals, and respondents do not even attempt to defend that Court's reasoning Respondents disown the Court of Appeals' decision and advance new theories in an effort to prevent a decision as to the validity of the regulations. These new theories are as erroneous as those advanced by the Court of Appeals.

[1] As to the venue issue in this case, no new contention not anticipated in petitioners' main brief (pp. 40-46) has been advanced by respondents, and nothing further need be said on that issue in this brief.

A. The Regulations Are Ripe for Review

Respondents concede (Res. Br. 46) that "the regulations involved in the present case are the product of mature administrative judgment, and are not merely preliminary or tentative agency conclusions." But in an effort to avoid the problem presented for them by the finality of the regulations, respondents say that enforcement of the regulations is in the hands of the Justice Department and for this reason they have "a preliminary cast." (Res. Br. 47 n.23). Certainly, if respondents and the Department of Justice were at loggerheads on the regulations, with the Department taking the position that it would not enforce them and would support anyone suing to enjoin their administrative enforcement by respondents, this might warrant a refusal to hold the regulations ripe for review. But this has not happened here. Respondents have been represented by the Justice Department in this case from its inception, and continue to be so represented in this Court, and, except for the Department here disowning some of the arguments made by respondents below, there has never been even a hint of anything but close harmony between respondents and the Department of Justice. Indeed, respondents' brief specifically negates any suggestion that the Attorney General would refuse to enforce the regulations. (Res. Br. 47 n.23).

Further, respondents' argument would make sense only if the Department of Justice had the *sole enforcement* authority, but this is not the case here, for respondents can also enforce the regulations.[2] Respondents in effect admit

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[2]Unlike the situation here, in neither Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), nor Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), was there any indication that the agency had any *independent* enforcement authority with respect to the action there challenged. In each case, the agency could only recommend enforcement to the Department of Justice and could not enforce

(Res. Br. 36 n.14, 41) that they will not clear for initial marketing drugs whose labels and labeling material do not comply with the regulations and will not permit the marketing of antibiotics not complying with the regulations. The suggestion that petitioners should simply violate the regulations and wait until they are sued, suffering without complaint administrative action which keeps safe and effective new products off the market, is irresponsible.

Under the statute, moreover, both criminal and civil sanctions are specified if the regulations are violated. These are severe. Petitioners would be subject to criminal prosecutions (21 U. S. C. § 333), to seizure proceedings (21 U. S. C. § 334), and to injunction actions (21 U. S. C. § 332).[8]

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its actions on its own. In any event, compare the later view of the District of Columbia Circuit in FTC v. Nash-Finch Co., 288 F. 2d 407 (D. C. Cir. 1961), where the Court upheld a challenge in a declaratory judgment action to an FTC ruling even though enforcement was only in the hands of the Department of Justice. The Court adopted the common-sense approach that the interests of the Justice Department could obviously be adequately represented in the suit against the agency.

[8]Petitioners are aware of respondents' representations as to the "policy" and "intention" of the Food and Drug Administration and that the Justice Department "will proceed only civilly" to enforce these regulations. (Res. Br. 41 and n.19). These representations, however, do not affect this case. First, it must be noted that the so-called "policy" of the FDA (and presumably the Justice Department) not to seek criminal sanctions when the underlying statute is subject to different readings has apparently not filtered down to the ranks of the FDA and the United States Attorneys, as the following recent criminal actions indicate. United States v. Abbott Laboratories, 66 CR. 584, N. D. Ill., information filed Sept. 19, 1966; United States v. The Upjohn Co., No. 7503, W. D. Mich., information filed Aug. 23, 1966.

Moreover, it is quite clear that even if the regulations could be enforced only administratively, this would suffice to render them ripe for review. Columbia Broadcasting System, Inc. v. United States, 316 U. S. 407 (1942); United States v. Storer Broadcasting Co., 351 U. S. 192 (1956). Indeed, even an agency's willingness to arrange a test case to determine the validity of regulations—and respondents' representations are a far cry from that—is not suffi-

This case is thus precisely the same as *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956), where regulations having "an immediate and practical impact" on private parties and enforceable either administratively or through court proceedings brought by the Department of Justice were held ripe for review. 351 U. S. at 43-44.[4] The fact that a decision there as to the validity of the regulations could have been obtained either in the administrative or court enforcement proceeding did not require the industry to wait until either type of proceeding was brought before challenging the regulations. See also *Columbia Broadcasting* and *Storer, supra*, and the Second Circuit's reading of these landmark cases in *Toilet Goods Ass'n*, 360 F. 2d 677, 685-86.[5]

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cient to preclude a direct challenge to regulations vitally affecting private interests. *Columbia Broadcasting, supra.* (See Res. Br. 52.)

Finally, belated representations to this Court cannot affect the question of whether the District Court was correct in holding the regulations ripe for review. *Cf.* American Life Ins. Co. v. Stewart, 300 U. S. 203, 215 (1937); Spector Motor Service, Inc. v. O'Connor, 340 U. S. 602, 605 (1951).

[4]Even the ICC's invitation to the Court in that case to decide the merits (see Res. Br. 54) is echoed in the statement of the FDA Commissioner at the time this suit was instituted that FDA welcomed actions challenging their regulations. (See Pet. Br. 13.)

[5]Respondents also mention the provision in § 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), for exemptions from the requirements of that section where compliance would be "impracticable". This provision, however, contemplates exemptions in individual situations, not where an entire industry challenges the legality of the "every time" requirement imposed by the respondents. In any event, as respondents acknowledge (Res. Br. 48 n. 24), the exemption provision applies only to the section of the regulations dealing with labeling and does not apply to the advertising section, the legality of which was also challenged in this action. See United States v. Storer Broadcasting Co., 351 U. S. 192 (1956) (regulation as to which waivers could be granted by FCC held ripe for review); United Gas Pipe Line Co. v. FPC, 181 F. 2d 796, 799-80 (D. C. Cir. 1950), *cert. denied*, 340 U. S. 827 (1950) ("if [exception from regulations] . . . furnishes only a partial remedy, or no remedy at all, . . . the proper forum is the district court"); 3 Davis, *Administrative Law* § 20.07 (1958).

Whether or not respondents are correct that "usually" the validity of regulations depends on factual variables (Res. Br. 49), respondents agree that in this case "the issue is purely legal and requires no weighing of testimony or other evidence" and that "the question would be purely one of statutory construction. . . ." (Res. Br. 55-56.) This purely legal issue, arising on cross-motions for summary judgment, is obviously an appropriate one for court review now. There certainly was no need for an inquiry into any factual issue in order for the District Court to determine whether the regulations are valid.

Of course, the District Court did not, after declaring these regulations invalid, go on to tell respondents what new regulations, if any, they should write. That is for the agency to determine; it, not the District Court, has the responsibility of administering the statute. All that any court can properly do is determine whether particular agency action is valid or invalid, not what further action, if any, the agency could or should take. *Cf. FPC* v. *Idaho Power Co.*, 344 U. S. 17, 20 (1952) ("function of the reviewing court ends when an error of law is laid bare"). Any asserted lack of "guidance" (Res. Br. 51) from the District Court's decision is thus no basis for saying that the issue presented was not appropriate for resolution by the District Court.[6]

The issue was and is clear-cut—whether respondents had statutory authority to promulgate regulations that a drug's established name must be repeated every time the drug's proprietary name is mentioned. In promulgating the regulations, respondents did not look at every piece of promotional material; under their view, this would be unnecessary because they claim that legislative history compelled their interpretation. Similarly, as the District Court noted (R. 40), there was no reason for it to make an individu-

[6]It is far from idle speculation to suggest that had the District Court attempted to issue some guidance to the respondents, respondents would probably be complaining of improper judicial intrusion into an area of their primary responsibility.

alized determination of the validity of the regulations as to each promotional piece.

The regulations represent an across-the-board determination which was invalidated by the District Court because the statute does not require an "every time" repetition of a drug's established name. The statute's requirements, the District Court determined, are couched in terms of prominence, rather than frequency of appearance, of the drug's established name.[7] The regulations were thus properly declared to be invalid. Of course, as respondents argue (Res. Br. 31-35), life would be easier for them if no court could ever declare regulations such as these invalid in this type of action. But respondents are not free to do as they please in administering the statute. Congress has set boundaries within which respondents must stay; it is the courts' function to see that these boundaries are respected by the respondents.

In short, the issue presented is the proper construction of a Federal statute, an issue that is clearly within the competence of Federal District Courts to decide. The issue was appropriately decided in this action since no relevant factual variables would be presented in any enforcement action. The District Court was as fully informed on this issue as would be any court in any future enforcement proceeding.

B. Congress Did Not Intend To Preclude Preenforcement Review of Any Regulations

Respondents have not met the burden of demonstrating that Congress intended to prohibit Federal courts from de-

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[7] This is also petitioners' view of the statute, and there has been no inconsistency in petitioners' position. Petitioners recognize that on some items—a multi-page product brochure, for example—the statutory requirement of "prominence" might call for more than one mention of the drug's established name. Petitioners so acknowledged in the District Court and have not departed from this position. Despite respondents' assertions (Res. Br. 30), there is nothing to the contrary in petitioners' brief in the Court of Appeals or in the petition for writ of certiorari.

termining in this type of litigation the legality of the regulations, an issue that is ripe for decision and wholly appropriate for judicial resolution.

Respondents do not argue that the statute itself, by its terms, precludes review of these regulations. Respondents rely exclusively on legislative history. The most that respondents can say about the legislative history, however, is that Congress "must have acted on the premise" (Res. Br. 6) and "must have assumed" (Res. Br. 22) that review of so-called "interpretive" regulations would not be available. Respondents' theories about what Congress "must have" done—not what it in fact did—cannot be said to be the required "clear and convincing evidence" of congressional intent to preclude review. See *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953) (quoting House Report on the Administrative Procedure Act); *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962).

On the contrary, both the statute and its legislative history are clear that Congress in 1938 intended its specification of the availability of review of certain "legislative" regulations to be an additional remedy in the case of the specified regulations and not an implied preclusion of traditional equity actions and actions under the then recently enacted Declaratory Judgment Act to challenge the legality of other regulations.

a. The Statute

Section 701(f)(6) of the Act, 21 U. S. C. § 371(f)(6), specifies that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." The House Report stated that this provision

> "saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to

> initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938), *Dunn* 825.[8]

There is nothing in the legislative history cited by respondents that even suggests that Congress had any different view of the "savings" clause in Section 701(f)(6).

Respondents, however, urge a "limited construction" (Res. Br. 27) of Section 701(f)(6)—that, contrary to its language and legislative history, Section 701(f)(6) applies only where review under Section 701(f)(1) is unavailable for the "legislative" regulations made reviewable under that section. Respondents advance two reasons. First, because earlier drafts did not explicitly preserve the right to institute equity and declaratory judgment proceedings, respondents say that Congress "viewed these rights narrowly." (Res. Br. 27). On the contrary, the fact that Congress thought it necessary, at a late stage in its consideration of the bill, specifically to preserve these rights shows that Congress was greatly concerned that the Act not be read to destroy the traditional rights of an industry which would be vitally affected by unlawful regulations.

Second, respondents note that the "savings" clause by its terms applies only to the judicial review provision specified in the Act. (Res. Br. 26-27). This is precisely the point. Congress provided in Section 701(f)(6) that the judicial review specified in the Act is "in addition to and not in substitution for" other remedies. Given this clear and unequivocal statement, it can hardly be contended that Congress intended the judicial review provision to operate also as an

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[8]The reference is to Dunn, *Federal Food, Drug, and Cosmetic Act* (1938), which contains the full legislative history of the 1938 Act.

implied limitation of judicial review, as respondents would have this Court hold.

b. The Legislative History

Despite respondents' assertions, the legislative history of the 1938 Act shows clearly that Congress contemplated that traditional judicial remedies would continue to be available in the case of *all* FDA regulations, and that Congress *added* to these remedies a statutory judicial review provision applicable to certain "legislative" regulations. This is demonstrated even by the legislative history materials relied upon by respondents which will be examined in turn.[9]

1. The "Tugwell bill" (S. 1944, 73d Cong., 1st Sess. (1933), *Dunn* 37-50), as respondents note (Res. Br. 12), authorized the adoption of regulations but made no specific provision for judicial review, and respondents apparently would have this Court infer that judicial review would have been unavailable. This is not the case. Senator Copeland, who introduced this bill (see *Dunn* 37), stated with respect to it, "There was no provision for review *except such as might come under the common law;* there was no

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[9]Respondents in their discussion of legislative history rely on Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950). (Res. Br. 24-26). What light a 1950 decision of this Court sheds on the intent of the Congress in 1938 is never explained, and respondents do not contend that this decision was brought to the attention of subsequent Congresses. In any event, in *Mytinger* this Court held that an FDA finding of "probable cause," made without a hearing, on the basis of which multiple seizures were instituted by the Justice Department, was not reviewable in a declaratory judgment action. The Court said that this finding, which the Court analogized to an indictment, represented a preliminary step in the initiation of judicial proceedings in which the company would be fully heard.

No preliminary finding of the FDA is involved in this case. Involved here are mandatory regulations, formally adopted and published, the validity of which presents an issue that is wholly appropriate for judicial resolution.

direct provision made for review." 78 Cong. Rec. 8958 (1934), *Dunn* 157. (Emphasis added.) Thus, even in the earliest version of the 1938 Act, it was recognized that any "common law" rights of judicial review were preserved.

2. Judicial review provisions were included in two successor bills (S. 2000, 73d Cong., 2d Sess. § 23 (1934), *Dunn* 66; S. 2800, 73d Cong., 2d Sess. § 23 (1934), *Dunn* 86). Senator Copeland explained that this was done because of fears that "common law" judicial review might be inadequate. 78 Cong. Rec. 8958-59 (1934), *Dunn* 157-59. Respondents never explain what bearing this has on the question of congressional intent to preclude review.

3. Respondents recite that a similar judicial review provision was included in S. 5, 74th Cong., 1st Sess. § 702 (1935), *Dunn* 200, which was reported by the Senate Commerce Committee with an amendment and approved by the Senate. Again respondents do not explain how this is helpful to their theory. (See Res. Br. 13.)

4. The House Interstate and Foreign Commerce Committee deleted the judicial review provision, explaining that it felt that

> "there was no reason to *add to the existing remedies* which are applicable. . . . There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, and furthermore . . . ample protection is given by the so-called Declaratory Judgments Act. . . ." H. R. Rep. No. 2755, 74th Cong., 2d Sess. 9 (1936), *Dunn* 557. (Emphasis added.)

This significant demonstration of lack of intent to preclude review is glossed over by respondents who say only that the

lack of a judicial review provision was attacked on the House Floor. (Res. Br. 13). They fail to state, however, that the basis of the attack was the claim that absent a judicial review provision a person affected by regulations could under traditional remedies obtain review only of questions of law and of whether the facts found were supported by substantial evidence, but could not otherwise obtain review of the facts. 80 Cong. Rec. 10243-44 (1936), *Dunn* 593-94. There was thus recognition by both those supporting and those opposing a specific judicial review provision that, even in its absence, the equity jurisdiction of the courts would be available.[10]

5. During the next Congress, consideration was given to the bill ultimately enacted as the Federal Food, Drug, and Cosmetic Act. S. 5, 75th Cong., 1st Sess. (1937), *Dunn* 636-55. It was reported to and passed by the Senate without any discussion relevant here. (See Res. Br. 15.)

6. The House Interstate and Foreign Commerce Committee again redrafted the bill. The House Committee bill provided, as the Act does now, for judicial review of certain "legislative" regulations and also contained the "savings" clause now found in Section 701(f)(6). See *Dunn* 810-11. The House Committee's view, it has already been

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[10]This was also the view of the Department of Justice, which stated with respect to a later bill:

> "[E]ven without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938), *Dunn* 934.

While respondents mention (Res. Br. 16) the Justice Department's opposition to a specific judicial review provision, they fail to recite the above basis of that opposition, which cannot be fitted within their legislative history theory.

noted (pp. 8-9, *supra*), was that the "savings" clause operated to preserve whatever rights existed to institute equity and declaratory judgment proceedings to challenge FDA regulations. This clear and explicit statement is dismissed by respondents who say that it was not sufficiently explained. (Res. Br. 16). It is difficult to see, however, how the congressional intent to preserve the right to institute this type of action could have been more explicit.

7. As respondents point out (Res. Br. 16-17), a minority of the House Committee objected to the judicial review provision, as did the Secretary of Agriculture. H. R. Rep. No. 2139, pt. 2, 75th Cong., 3d Sess. (1938), *Dunn* 834-38. Respondents fail to point out, however, that the minority noted that the method of review provided in the bill "is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act." *Id.* at 1, *Dunn* 834. The minority and the Secretary went on to object to what they viewed as a new form of judicial review which they felt went beyond existing law.[11] The same criticism was expressed on the House Floor by Congressman Mapes, who signed the minority report, in a statement cited, but understandably not quoted, by respondents (Res. Br. 17):

> "The particular provision in the bill to which I am opposed is . . . paragraph (f) of section 701: That does not mean that I am opposed to any court review. Not at all. Everyone concedes the right of an aggrieved person to a court review, or his day in court, but not such a court review as the one provided for

[11]The Court in *Toilet Goods Ass'n*, 360 F. 2d 677, 684 n.7, similarly read the minority report. It was viewed as indicating that "the special [review] procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency."

in the committee substitute." 83 Cong. Rec. 7772 (1938), *Dunn* 842.

8. Congressman Mapes, who emerged as the spokesman for those opposed to the judicial review provision reported by the House Committee, then offered an amendment designed to satisfy the objections of the Secretary of Agriculture to that provision. 83 Cong. Rec. 7891, 7892 (1938), *Dunn* 931-32, 933.[19] During the debate on his amendment, which was supported by the only other signer of the minority report who spoke to the point, 83 Cong. Rec. 7896 (1938), *Dunn* 944, Congressman Mapes repeated that:

> "[U]nder existing law any individual may go into the district court in which he resides for the purpose of obtaining an injunction against any order of the Food and Drug Administration that applies to him, that is arbitrary, capricious, unreasonable, or contrary to law, and that will cause him irreparable damage. *No one proposes to take that right away from anyone.*" 83 Cong. Rec. 7893 (1938), *Dunn* 936. (Emphasis added.)

And he said again:

> "The injunction matter is outside of both of these provisions. *The injunction remedy by any aggrieved person is had without reference to the provisions in the bill or to my amendment.*" 83 Cong. Rec. 7894 (1938), *Dunn* 938. (Emphasis added.)

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[19] Although, as respondents point out (Res. Br. 18, 31 n.13), the amendment, providing among other things for review in the Courts of Appeals instead of the District Courts, was rejected on the House Floor, 83 Cong. Rec. 7898 (1938), *Dunn* 950, respondents fail to mention that review in the Courts of Appeals was provided for in the bill as reported by the Conference Committee and as enacted. H. R. Rep. No. 2716, 75th Cong., 3d Sess. 17 (1938), *Dunn* 987.

Respondents seek to minimize the importance of these statements—bearing directly on the issue here—by noting (Res. Br. 31 n.13) that Representative Leavy said that the doctrine of sovereign immunity would bar actions against those administering the Act. 83 Cong. Rec. 7895 (1938), *Dunn* 941. Respondents fail to point out that this conclusion was disputed by Representative Sauthoff. *Ibid.* The important point here, however, is that even respondents do not say that anyone contradicted Representative Mapes' statement that neither the Committee bill nor his amendment had any effect on any person's right to obtain an injunction against FDA regulations, the position also taken in the House Report and recognized in the minority report.

9. Differences between the House and Senate bills were resolved in conference, and respondents note (Res. Br. 18) that the Conference Committee stated that "legislative" regulations would be reviewable under the Act. But the Committee did not say that other regulations would not be reviewable. And the lack of any negative implication is shown by the Committee's specific statement that there was retained in the Conference bill "the provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies. . . ." H.R. Rep. No. 2716, 75th Cong., 3d Sess. 25 (1938), *Dunn* 995-96.

Petitioners submit that this legislative history is crystal clear and confirms the express statutory declaration that the judicial review specified in the Act is solely an additional, non-exclusive remedy in the case of certain regulations. The legislative history shows that Congress did intend to distinguish between "legislative" regulations reviewable under Section 701(f) and other FDA regulations. But the distinction was not between reviewability of the former regulations and nonreviewablity of the latter, as respondents contend. Nowhere in the legislative history is

there even any suggestion of any intent to preclude review of any regulations. It was continually acknowledged that any FDA action could be challenged in a declaratory judgment or injunction action, if the requirements applicable to these types of proceedings were met. The distinction was between those "legislative" regulations made specifically reviewable under a special procedure in the courts of appeals and other regulations as to which the only available remedy would require satisfaction of the requirements applicable to all equity and declaratory judgment actions.[18]

The specification of judicial review in the Act is not rendered superfluous, as respondents contend, by the fact that Congress did not contemplate precluding preenforcement review of other regulations. Where regulations are not covered by a specific judicial review provision, there are many obstacles that must be overcome in order to obtain review. This case is a good example. Respondents moved to dismiss this case in the District Court, alleging four separate grounds of dismissal—the lack of an "actual controversy," failure to join an indispensable party, no review of "interpretive" regulations, sovereign immunity—as well as complaining that venue was improper for 26 petitioners. (R. 19-21.) Obstacles such as these to immediate review are eliminated in the case of regulations made reviewable under Section 701(f) of the Act. The judicial review pro-

[18]Nothing in the subsequent amendments to the Act relied upon by respondents (Res. Br. 28-30) calls for any different conclusion. These amendments, in respondents' words (Res. Br. 29), "specified the regulations which are subject to judicial review either under Section 701(f) or under specific provisions in the amendments and have been silent as to all others." Congressional silence is no evidence of any intent to preclude review. Heikkila v. Barber, 345 U. S. 229, 232 (1953). See Jaffe, *Judicial Control of Administrative Action* 357 (1965):

> "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent."

vision thus serves an important function even though regulations such as those involved here are not barred *ab initio* from judicial consideration when they are promulgated.

II. THE REGULATIONS ARE WITHOUT STATUTORY BASIS

Respondents contend that the "every time" regulations are "interpretive". As such, the question on the merits can be put very simply: Does the statute require an "every time" mention of the established name? If it does not, then the regulations are invalid, for it is clear that respondents cannot, in the guise of interpreting a statute, impose a requirement not imposed by the statute itself, whether or not respondents have the proverbial "expertise" or the regulations are "reasonable". This was made clear in *FCC v. American Broadcasting Co.*, 347 U. S. 284 (1954), in which "interpretive" regulations of the FCC which prohibited the broadcasting of "give-away" programs were invalidated:

> "The question presented is whether the . . . provisions correctly interpret § 1304 of the United States Criminal Code [which] . . . prohibits the broadcasting of '. . . any lottery. . . .'
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> * * *
>
> "[T]he Commission's power . . . is limited by the scope of the statute. Unless the 'give-away' programs . . . are illegal under § 1304, the Commission cannot employ the statute to make them so by agency action." 347 U. S. at 285, 290.

Here, as will be shown below, the statute cannot be read as imposing an "every time" requirement, and the legislative history does not show that Congress intended to impose this requirement.

A. The Statutory Language Precludes Respondents' Interpretation

Section 502(e)(1)(A) of the Act, 21 U. S. C. § 352 (e)(1)(A), declares a drug to be misbranded unless "its

label bears . . . the established name . . . of the drug. . . ." With respect to "any prescription drug," Section 502(e)(1)(B) of the Act requires that on labels "and on any labeling on which a name for such drug . . . is used," the established name of the drug must be "printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ." The language of Section 502(n) of the Act, 21 U. S. C. § 352(n), which applies to advertising, is similar. All advertisements for a prescription drug must include "a true statement of . . . the established name . . . printed prominently and in type at least half as large as that used for any trade or brand name thereof. . . ."

It is perfectly clear that this language, by its plain terms, does not require an "every time" repetition of a drug's established name. Had Congress intended an "every time" requirement, it could very easily have written this requirement into the statute. It did not do so. Congress required only that the established name be printed "prominently" and in type half as large as that used for "any" proprietary name. The logical reading of "any", the only possible ambiguity in the statute, is that if on a piece of labeling, for example, the proprietary name is mentioned four times, the type size of the established name must be half as large as the type size used for "any" printing of the proprietary name. In this event, the type size would have to be half as large as the largest type used in mentioning the proprietary name. "Any" also has the effect of obviating the type-size requirement where no proprietary name is printed, as well as covering the case where two or more different proprietary names appear in a single promotional piece.

Respondents suggest that "any" be read to mean "all". However, this does not help the respondents; even if "all" were substituted for "any", the respondents' interpretation would not follow, for the statute would read: The

established name must be "printed prominently and in type at least half as large as that used for *all* proprietary name[s] or designation[s]. . . ." It will be noted that even this perversion of the statutory language does not call for an "every time" repetition. It would require that if, for example, on a piece of labeling the proprietary name is mentioned four times, the established name's type size must be half as large as that used for all four mentions of the proprietary name. Congress scarcely intended this result and, in any event, it does not help the respondents.

Finally, it must be noted that the type size requirement is not the only requirement contained in the statute. The statute also requires that the established name must be printed "prominently". In light of the "prominently" requirement, which serves to bring established names to the attention of physicians, an "every time" requirement is superfluous. And, if an "every time" requirement is to be read into the statute, the requirement of "prominently" is superfluous. As the District Court determined:

> "If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word 'prominently'. The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary." (R. 54).

Thus, the argument that the "every time" requirement is contained in the statute runs counter to the most elementary principle of statutory construction, which requires that effect be given to all parts of a statute. *E.g., United States v. Menasche,* 348 U. S. 528, 538-39 (1955).[14]

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[14]Respondents' efforts to find some use for the "prominently" requirement if the statute requires an "every time" repetition of the established name are ingenious but unavailing. Respondents' sugges-

The basic difficulty with respondents' position is that the statute, which specifies criminal sanctions for its violation, requires only that the established name appear, that it appear "prominently", and that it appear in a specified size of type. No amount of tortuous verbalizations can succeed in having these statutory provisions read as dealing with the number of times the established name must appear.

B. The Legislative History Does Not Show That Congress Intended an "Every Time" Requirement

Respondents are forced to rely on legislative history in an effort to have the statute bear the interpretation which they have adopted. In doing so, they seize upon two isolated items—in fact, on two mentions of the one word "wherever" (Res. Br. 60)—in the extensive legislative history of the 1962 amendments to the statute and argue that these demonstrate conclusively that Congress intended an "every time" requirement. Even these two items, however, are directly contradicted by other items in the legislative history. Moreover, as the District Court found, there was no "general Congressional intent" to impose an "every time" requirement. (R. 55.)

a. "Wherever" in the Senate Report

The first use of the word "wherever" relied upon by respondents is in the Senate Judiciary Committee Report. The Committee Report states:

> "It [the Committee amendment] would . . . require that on labels and on any labeling, *wherever* a trade or brand name is used, the established name, as defined in this section, must be shown in type at least

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tion (Res. Br. 58) that Congress inserted the "prominently" requirement "to insure against the ingenuity of advertising and layout designers" is simply their theory. They cite no legislative history in support of this theory.

> one-half as large as that used for the trade or brand name." S. Rep. No. 1744, pt. 2, 87th Cong., 2d Sess. 8 (1962). (Emphasis added.)

By emphasizing one word in a Committee Report, which of course does not receive the same degree of attention that is devoted to drafting legislation, the respondents are grasping for straws. First, if the Report is to be construed as a statute, "wherever" must apply to its antecedents in the Report, *i.e.*, labels and labeling, and "wherever" would refer only to each label and piece of labeling. So read, "wherever" does not connote frequency of appearance on any particular item, but only requires that the established name must appear on each label and piece of labeling bearing a proprietary name.

Moreover, even if, as the respondents suggest, "wherever" in the Report should be construed as meaning "every time", this reading of "wherever" is squarely contradicted by the prepared statement of Senator Eastland, Chairman of the Senate Committee, in which he explained the bill on the Senate Floor two days after the Report was issued. Senator Eastland stated:

> "On the label, and on any labeling on which the drug . . . is named, *if* a trade name is used for the drug . . ., the established name of the drug . . . must be shown in type at least half the size of the type used for the trade name." 108 Cong. Rec. 17366-67 (1962). (Emphasis added.)

Senator Eastland's statement is similar to the language in the Senate Report, with one significant difference. Senator Eastland used the word "if" where the Senate Report used the word "wherever". Even if "wherever" can be read as meaning "every time", the word "if" certainly has no such connotation. In light of this difference between the language

in the Senate Report and that used by the Chairman of the Committee in a prepared statement on the Senate Floor, it cannot be contended that "wherever" in the Report is a compelling statement of congressional intent. See *Chicago, M., St. P. & Pac. R. R.* v. *Acme Fast Freight, Inc.*, 336 U. S. 465, 475 (1949) (Report contradicted by explanatory floor statement "can hardly be considered authoritative").

b. Senator Kefauver's "Wherever"

The other use of the word "wherever" relied upon by respondents occurred during Senator Kefauver's explanation of the Conference Committee's rejection of an amendment proposed by Congressman O'Brien, which had been adopted by the House.

As reported by the House Interstate and Foreign Commerce Committee, the bill would have amended Section 502(e) of the Act to require that

> "for any prescription drug the established name of such drug . . . on such label [must be] . . . printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ." H. R. Rep. No. 2464, 87th Cong., 2d Sess. 64 (1962).

During the debate in the House, Congressman O'Brien offered an amendment, to which no objection was noted, which made two changes in the bill as reported. The first change was to extend the requirement as to the size of the established name to labeling, since the bill applied only to a drug's label. The second change was to insert a provision that, in the case of labeling, the requirement that the established name be printed prominently and in half-size type was applicable "at the first place, and at the most conspicu-

ous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

This second aspect of the O'Brien amendment was rejected in conference. Senator Kefauver's explanation of the rejection was that the amendment

> "was a limitation upon the frequency with which the established name should appear in labeling. . . . This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name *wherever* the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962). (Emphasis added.)

Neither the rejection of the amendment nor Senator Kefauver's explanation of that rejection is any demonstration of a congressional purpose to impose an "every time" requirement.

First, the rejection of the amendment does not necessarily reflect congressional approval of the opposite of the rejected proposal. *Cf. Girouard* v. *United States*, 328 U. S. 61, 69-70 (1946); *United States* v. *South-Eastern Underwriters Ass'n*, 322 U. S. 533, 560-61 (1944); *Cleveland* v. *United States*, 329 U. S. 14, 22-23 (1946) (concurring opinion). Moreover, even if "psychoanalysis of Congress"[15] is a proper function of the judiciary and it is assumed that Congress intended the opposite of the O'Brien amendment, it does not follow that the intent of the conferees when they rejected the O'Brien amendment was to impose an "every time" requirement. "Every time" is not necessarily the "opposite" of the O'Brien amendment. Its rejection

[15] United States v. Public Util. Comm'n, 345 U. S. 295, 319 (1953) (Jackson, J., concurring).

could mean, at most, that the required mention of the established name specified in the O'Brien amendment was not necessarily sufficient, not that "every time" was imperative.

Second, so far as Senator Kefauver's statement is concerned, the District Court dealt with it correctly. The Court noted that "Kefauver's term 'wherever' is not free from ambiguity." (R. 55). That this conclusion was valid has already been discussed in connection with "wherever" as used in the Senate Report (pp. 20-21, *supra*). The Court also stated that "it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate." (R. 55). This conclusion is supported by the Report of the House Managers on the Conference Committee. This Report is directly contrary to Senator Kefauver's statement as to the nature of the O'Brien amendment and, thus, as to the effect of the Conference Committee's rejection of that amendment. The House Managers stated:

> "Both the House amendment and the Senate bill in the section relating to the use of official names on the labels and the labeling of prescription drugs provided that the established name of a drug . . . must be printed on any label or labeling prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . . With regard to labeling on prescription drugs the House amendment *further provided* that the established name of the drug . . . must be *so* printed at the first place and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used.
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> "The Senate version did not contain the second provision with regard to labeling.
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> "The conference substitute adopts the Senate version." H. R. Rep. No. 2526, 87th Cong., 2d Sess. 23-24 (1962). (Emphasis added.)

There is no indication in this Report that the House Managers construed the O'Brien amendment as a *limitation* upon the number of times the statute would require the established name to be mentioned. On the contrary, the Report treats the provision relating to the place where the established name must appear as an *additional* requirement, one not already imposed by the bill. This view is, of course, consistent with the first aspect of the O'Brien amendment, noted above, which *extended* the bill to cover labeling. The second aspect of the amendment similarly was an extension of the bill and not a limitation as to its reach. The O'Brien amendment having been rejected in conference, the bill remained as previously reported—dealing only with the conspicuousness with which the established name must be printed and not with the number of times it must be mentioned.[16]

c. The Congressional Purpose

By no stretch of the imagination can the two mentions of the word "wherever"—the legislative history exclu-

[16]Respondents also cite Congressman O'Brien's observation during a subsequent Congress on the Conference Committee's rejection of his amendment. (Res. Br. 60.) This, however, is not part of the legislative history of the 1962 drug amendments at all since it occurred *after* the statute was passed and, indeed, *after* the proposed regulations, which incorporated an "every time" requirement, were issued. And "statutes are construed by the courts with reference to the circumstances existing at the time of the passage." United States v. Wise, 370 U. S. 405, 411 (1962). See also SEC v. Capital Gains Research Bureau, Inc., 375 U. S. 180, 199-200 (1963); United States v. Philadelphia Nat'l Bank, 374 U. S. 321, 348-49 (1963); United States v. Price, 361 U. S. 304, 313 (1960); Ramspeck v. Federal Trial Examiners Conference, 345 U. S. 128, 143 n.9 (1953); Fogarty v. United States, 340 U. S. 8, 13-14 (1950); United States v. United Mine Workers, 330 U. S. 258, 281-82 (1947). In addition, all that Congressman O'Brien said was that he was on the Conference Committee and that the Committee rejected his amendment. For reasons already noted, the rejection of that amendment does not support the respondents' contention that Congress intended an "every time" requirement.

sively relied upon by respondents—be said to demonstrate that there was a general congressional intent to impose an "every time" requirement. The lack of any such intent is shown by one simple fact: Although both Houses of Congress gave extensive consideration to the precise statutory language dealing with the required display of a drug's established name,[17] not once did any legislator say anything to the effect that "This means that the established name must be repeated each time the drug's brand name is mentioned." This is not an abstruse, difficult concept to grasp or articulate and it requires no sophisticated, subtle thinking. Certainly, if Congress had intended this "every time" requirement it could very easily have been spelled out in specific terms, if not in the statute, then at least in the

[17]The relevant language was repeatedly being changed as the various bills went through the legislative mill. As introduced by Senator Kefauver on April 12, 1961, S. 1552 required that a drug's "official name" be "printed *in type at least as large and as prominent* as that used for any trade or brand name. . . ." S. 1552, 87th Cong., 1st Sess. §§ 4(a)(4), 4(a)(7) (1961). (Emphasis added.) H. R. 11581, introduced by Congressman Harris on May 3, 1962, required that a drug's established name be "given *precedence in position* over any proprietary name . . . for such drug . . . and [be] . . . *in type at least as large and prominent* as that used for such proprietary name. . . ." H. R. 11581, 87th Cong., 2d Sess. § 112 (a)(4) (1962). (Emphasis added.) Section 9(a) of S. 1552 as reported by the Senate Judiciary Committee on July 19, 1962, required a drug's official name to be *"printed in a manner complying with subsection (c)* of this section. . . ." See S. Rep. No. 1744, 87th Cong., 2d Sess. 6 (1962). (Emphasis added.) (The reference is to § 502(c) of the Act, 21 U. S. C. § 352(c), which requires statements on labels and labeling to be "prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.") Thereafter, the President suggested an amendment to S. 1552 that required a drug's official name to be "printed *prominently* and *in type at least half as large* as that used for any trade or brand name. . . ." See 108 Cong. Rec. 15697 (1962). (Emphasis added.) This language as to type size was subsequently adopted by the Senate Judiciary Committee and by the House Interstate and Foreign Commerce Committee and was enacted into law.

legislative history. The lack of any clear and explicit statement in the legislative history that "every time" was intended shows that this requirement was not contemplated by the Congress.

The legislative history does reveal, as the District Court determined (R. 53), that Congress was concerned that there be a prominent and conspicuous display of the drug's established name. This would enable physicians to become aware of a drug's established name so that, if they wished to do so, they could prescribe on that basis rather than by the drug's brand name. Congress did not, however, express any intention of forcing established names down a doctor's throat by imposing an "every time" requirement.

Senator Kefauver, for example, in introducing S. 1552, made no reference to any "every time" requirement. The purpose of the relevant provision of the bill (n.17, *supra*), he said, was "to help the physician to identify the family to which the drug belongs by showing clearly the official name of the product. . . ." 107 Cong. Rec. 5640 (1961). The same concern with nondisclosure of the established name and with the need for prominent disclosure was expressed in his minority views and those of Senators Carroll, Dodd, Hart, and Long on S. 1552 as originally reported by the Senate Judiciary Committee (see n.17, *supra*). S. Rep. No. 1744, 87th Cong., 2d Sess. 38-39, (1962). Senator Kefauver again criticized the omission or lack of conspicuousness of established names in advertisements and labeling when he supported S. 1552 as amended by the Committee, and he went on to say that "doctors would be able to see more readily the generic name of drugs, if they are in larger type." 108 Cong. Rec. 17369 (1962).[18]

[18]In this connection, it must be emphasized that the statutory requirement is applicable only to prescription drugs, and that labels, labeling, and advertising matter for these drugs are directed to

The point here is that there was no mention in any of these statements of an "every time" requirement—the purpose was simply to prevent nondisclosure of the established name. Nor did the two other Senators who spoke on the established name provision during the Senate Floor debate mention an "every time" requirement. See 108 Cong. Rec. 17366-67 (1962) (remarks of Senator East[illegible]); *id.* at 17383 (remarks of Senator Hart). Similarly, there was no reference to an "every time" requirement during the House debate.

In short, the legislative history reveals, [illegible] the District Court (R. 53-54), that Congress [illegible]erned about nondisclosure of established name[illegible] they were disclosed, the small type in which they [illegible]nted. Congress chose an appropriate remedy by requiring that the established name appear conspicuously on labels, labeling, and advertisements—*i.e.*, that it appear "prominently and in type at least half as large as that used for any" proprietary name. Congress did no more than this. There is nothing to indicate congressional concern over the frequency of appearance of the established name, and nothing to indicate that Congress intended an "every time" requirement.

CONCLUSION

The judgments of the Court of Appeals should be reversed. The case should be remanded to the Court of Appeals for a determination of the merits. If, however, this

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physicians and not to the general public. (R. 8). In the absence of legislative history to the contrary, it can hardly be assumed that Congress believed that physicians, who are highly trained and knowledgeable in this area, would require an "every time" repetition of a drug's established name in order to become aware of that name. While constant repetition may be desirable for children learning the multiplication tables, it is wholly inappropriate and unnecessary for physicians, and can easily be distracting and annoying to any careful reader. (R. 14-15.)

Court should determine the merits, the judgment of the District Court (except as to its venue ruling) should be affirmed.

Respectfully submitted,

GERHARD A. GESELL
701 Union Trust Building
Washington 5, D. C.
Attorney for Petitioners

Of Counsel:

STANLEY L. TEMKO
HERBERT DYM
COVINGTON & BURLING
701 Union Trust Building
Washington 5, D. C.

HAYWARD H. COBURN
DRINKER BIDDLE & REATH
1100 Philadelphia National
Bank Building
Broad and Chestnut Streets
Philadelphia 7, Pennsylvania
Attorney for Merck & Co., Inc.

LLOYD N. CUTLER
MARSHALL HORNBLOWER
WILMER, CUTLER & PICKERING
900 17th Street, N. W.
Washington 6, D. C.

C. JOSEPH STETLER
JOHN K. WORLEY
Pharmaceutical Manufacturers
Association
1155 15th Street, N. W.
Washington 5, D. C.
*Attorneys for Pharmaceutical
Manufacturers Association*

ALEXANDER L. NICHOLS
WILLIAM S. MEGONIGAL, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL
3000 DuPont Building
Wilmington 1, Delaware
Attorneys for Petitioners